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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/760,136
Filing Date: January 12, 2001
Appellant(s): NUSS, STEPHEN

Thomas J. Nikolai
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/24/05 appealing from the Office action mailed 5/05/2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: Claims 12, 16 – 20 and 24 – 27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,776,330 to **Chapman et al. in view of** U.S. Patent No. 6,132,389 to **Cornish et al.** Additionally, claims 12, 16 – 20 and 24 – 27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,132,389 to **Cornish et al in view of** U.S. Patent No. 4,776,330 to **Chapman et al.**

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12, 16 – 20 and 24 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,776,330 to Chapman et al. in view of U.S. Patent No. 6,132,389 to Cornish et al.

In regards to claims 12, 16 – 20 and 24 – 27, Chapman et al. discloses a guidewire capable of insertion into a vascular system of a patient during the course of a catheterization procedure having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight (Col. 4, lines 16 – 23; Col. 11, line 67 – Col. 12, line 2; Col. 13, lines 61 – 63), but fails to disclose the guidewire having a tapered distal end portion, a helical coil attached to the distal end, a rounded distal tip member on the distal end, a polymeric or a hydrophilic coating, or a diameter in the range of 0.005 inch and 0.040 inch. However, Cornish et al. discloses a guidewire having a tapered distal end portion (18), a helical coil (20) attached to the distal end, a rounded distal tip member (58) on the distal end, a polymer coating and a hydrophilic coating (Col. 3, lines 50 – 60), and a diameter in the range of 0.005 inch and 0.040 inch (Col. 4, lines 19 – 28). It would have been obvious to one

having ordinary skill in the art at the time the invention was made to modify the guidewire as disclosed by Chapman et al. to include a tapered distal end portion as taught by Cornish et al. in order to increase the flexibility of the distal end of the guidewire. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as disclosed by Chapman et al. to include a helical coil attached to the distal end as taught by Cornish et al. in order to facilitate fluoroscopic viewing of the device while in use and to increase the diameter of the distal section without adding substantial stiffness to the section (Col. 4, lines 36 – 45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as disclosed by Chapman et al. to include a rounded distal tip member on the distal end as taught by Cornish et al. in order to attach the helical coil to the guidewire and o further smooth the transition from the guidewire to the helical coil (Col. 5, lines 5 – 12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as disclosed by Chapman et al. to include a polymeric or a hydrophilic coating as taught by Cornish et al. in order to increase the lubricity of the guidewire (Col. 3, lines 50 – 60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the diameter of the guidewire as disclosed by Chapman et al. to be in the range of 0.005 inch and 0.040 inch as taught by Cornish et al. or to be any diameter as since applicant has not disclosed that using a diameter in the range of 0.005 inch and 0.040 inch provides any advantage, or solves a stated problem, or is used for any particular purpose. Furthermore, a change in the size of a prior art device is a design consideration within the skill of the art. ***In re Rose***, 220 F.2d 459, 105 USPQ 237 (CCPA 1955).

Claims 12, 16 – 20 and 24 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,132,389 to Cornish et al. in view of U.S. Patent No. 4,776,330 to Chapman et al.

In regards to claims 12, 16 – 20 and 24 – 27, Cornish et al. discloses an intravascular guidewire adapted for insertion into the vascular system of a patient during the course of a catheterization procedure (Col. 1, lines 20 – 67) having a tapered distal end portion (18), a helical coil (20) attached to the distal end, a rounded distal tip member (58) on the distal end, a polymer coating and a hydrophilic coating (Col. 3, lines 50 – 60), and a diameter in the range of 0.005 inch and 0.040 inch (Col. 4, lines 19 – 28). Cornish et al. discloses the wire being formed of a titanium alloy but fails to disclose the titanium alloy being a titanium molybdenum alloy having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight. Chapman et al. discloses a guidewire capable of insertion into a vascular system of a patient during the course of a catheterization procedure having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight (Col. 4, lines 16 – 23; Col. 11, line 67 – Col. 12, line 2; Col. 13, lines 61 – 63), It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the titanium alloy as disclosed by Cornish et al. to include a titanium molybdenum alloy having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight as taught by Chapman et al. in order to provide a resilient, physiologically inert guidewire (Col. 4, lines 16 – 23).

(10) Response to Argument

Applicant begins by asserting that Chapman et al. '330 fails to indicate that the guidewire (25) is formed of the claimed titanium, molybdenum alloy. However, the Examiner disagrees. At column 4, lines 16 – 23, Chapman et al. states that each of the components of the kit are made of a

resilient, physiologically inert titanium-based alloy such as Ti - 11.5Mo - 6Zr - 4.5Sn. At column 11, line 67 – column 12, line 2, Chapman et al. states that all of the implants shown in Figures 1 to 32B are made of a resilient, physiologically-inert titanium-base alloy (i.e. Ti - 11.5Mo - 6Zr - 4.5Sn). In Figures 4 – 6, Chapman et al. shows a guidewire (25) and goes on to explain at column 13, lines 61 – 63 that the guidewire is left in place in the patient's bone to form part of the implant. The Examiner has concluded that because the guidewire (25) forms a part of the implant, that it must be a part of the kit and therefore be formed of the resilient, physiologically inert titanium-based alloy.

In regards to the rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,132,389 to Cornish et al. in view of U.S. Patent No. 4,776,330 to Chapman et al., Applicant asserts that nickel sensitivity is not a problem with coronary guidewires and that such a problem is not a motivation for modification of Cornish et al. Applicant states that there is no suggestion to combine the references. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation provided by the Examiner to produce the claimed invention comes directly form the Chapman et al. reference at Col. 4, lines 16 – 23. The Examiner concluded that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the titanium alloy as disclosed by Cornish et al. to include a titanium molybdenum alloy having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight as taught by Chapman et al. in order to provide a resilient, physiologically inert guidewire (Col. 4, lines 16 – 23). A kinked guidewire can be problematic when advancing into

a patient. One having ordinary skill in the art would see the advantage of having a resilient, physiologically inert guidewire to avoid problems with permanent deformation. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Again, the teaching to modify the titanium alloy as disclosed by Cornish et al. comes directly from the teaching of the claimed alloy being a resilient and physiologically inert alloy. Applicant asserts that the guidewire as disclosed by Chapman et al. is incapable of insertion into a vascular system of a patient during the course of a catheterization procedure. However, such a limitation provides no structural difference in the claimed invention and the guidewire as disclosed by Chapman et al. It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. ***In re Pearson***, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); ***In re Casey***, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); ***In re Otto***, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. ***In re Ludtke***, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may be an inherent characteristic of the

prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. ***In re Spada***, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); ***In re King***, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); ***In re Ludtke***, 441 F.2d 664, 169 USPQ 566 (CCPA 1971). In the present case the guidewire as disclosed by Chapman et al. is fully capable of being inserted into a vascular system of a patient during the course of a catheterization procedure. As such, one having ordinary skill in the art would look to other guidewires as a means to improve the functionality of the guidewire as disclosed by Chapman et al. The requisite pushability, torqeability and malleability are characteristics inherent to the titanium-molybdenum alloy guidewire disclosed by Chapman et al.

For the above mentioned reasons and the fact that Applicant has failed to produce evidence or arguments to show nonobviousness of the claimed invention, the Examiner maintains that the rejections of claims 12, 16 – 20 and 24 – 27 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,776,330 to Chapman et al. in view of U.S. Patent No. 6,132,389 to Cornish et al. and claims 12, 16 – 20 and 24 – 27 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,132,389 to Cornish et al in view of U.S. Patent No. 4,776,330 to Chapman et al. are proper and render the claimed invention obvious.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Respectfully submitted,

JMLF

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